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Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: Protocol of a patient and public involvement project

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Title: Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: Protocol of a patient and public involvement project

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ABSTRACT

Introduction A patient and public involvement (PPI) project is embedded within the SALuBRITY pilot trial, a two parallel group, double sham controlled, randomised clinical trial. The study aims to compare the effectiveness of spinal manual therapy and corticosteroid nerve root injections, two methods commonly used to treat patients with lumbar radiculopathy. We aim to gather patients' and clinicians' perspectives and involve them in decisions related to the research question and objectives, proposed trial recruitment processes and methods, and proposed outcome measures.

Methods and analysis A small group of patients with lived experience of lumbar radiculopathy and primary care clinicians with experience in the treatment of patients with lumbar radiculopathy are involved. An initial kickoff event prepares and empowers the advisors for involvement in the project, followed by semi-structured patient group and one-on-one clinician interviews. We follow the Critical Outcomes of Research Engagement (COREs) framework for assessing the impact of patient engagement in research. We will summarize and feedback PPI content to the patient and clinician advisors during a member-checking process to ensure accurate interpretation of patient and clinician inputs. Inductive and deductive thematic analysis will be used for the qualitative analysis of the interviews. Two surveys are meant to be completed at different points along the trial, in order to track the advisor's and researcher's experience over the course of the PPI project. Any modifications to the SALuBRITY trial methods as a result of PPI inputs will be thoroughly documented and recorded in an impact log.

Ethics and dissemination The SALuBRITY pilot trial will be submitted for ethical review and approval by the independent research ethics committee of Canton Zurich. The research ethics board confirmed that ethical approval for the PPI subproject is not required. PPI results will be disseminated in peer-reviewed journals and presented at conferences.

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Strengths and limitations of this study:

- This PPI project is an important step for making research more relevant to end-users and facilitating research translation into clinical practice.
- Existing frameworks guide consultation and collaboration approaches and draw our attention to relevant outcomes to evaluate the impact of PPI activities.
- Patient and clinician advisors will be supplied with detailed information about PPI in general and the future trial to be empowered for their contribution to the project.
- Sample size is small and inadequate for quantitative analysis but allows a pragmatic qualitative approach and recognition of multiple individual realities.

INTRODUCTION

Patients' role in research has changed over the past decades from being study participants to getting engaged at different levels and in different stages of research.

The value of patient and public involvement (PPI) is increasingly recognized and prioritized by research regulators and funders,[1–3] academic journals,[4] and patient organizations.[5] The INVOLVE initiative, established in 1996 and funded by the National Institute for Health Research (NIHR) of the United Kingdom, was taken over by NIHR Center for Engagement and Dissemination in 2020 and defines public involvement as research carried out “with” or “by” members of the public rather than “to”, “about” or “for” them.[6] PPI represents an essential approach for keeping the research relevant to end-users (e.g., patients and clinicians) and improving its translation into real-world clinical practice by integrating patient and clinician perspectives on the relevant research topic.

Back-related leg pain affects about 200 million people worldwide, and was estimated to account for up to 35 million years lived with disability in 2017.[7] Lumbar radiculopathy—arising from lumbar spinal nerve root compression or irritation—is characterized by low back pain (LBP) that radiates down the leg in a lumbar nerve distribution.[8] With increased pain and disability, people suffering from back-related leg pain have poorer prognosis, quality of life and an increased use of health resources compared to people with LBP alone.[9] Spinal manual therapy (SMT) and corticosteroid nerve root injection (NRI) are two common conservative treatment methods in routine clinical care, but there is uncertainty regarding their effects. To assist patients, clinicians, and policymakers with decision-making on the treatment of lumbar radiculopathy based on high quality evidence, the SALuBRITY pilot trial – a two parallel group, double sham controlled, randomised clinical trial – is being developed.

PPI involvement in the development phase of a clinical trial can help to identify possible challenges in the collaboration of researcher with patients at an early stage, with all involved people facing beneficial impacts. Researchers profit from extended funding, better enrollment rates [10,11] and increased trust and advocates within the community under research.[12] Patients describe empowerment, increased knowledge and confidence, which emphasize the wide societal benefits and the potential for research to act as a positive force in society.[12] In recognition of these benefits – ultimately

leading to improved quality and relevance of the research being conducted – we will carry out a PPI project nested in the SALuBRITY trial, aiming to improve the quality and relevance of the future trial.

Our goal is to enhance the quality of care and quality of life for patients with lumbar radiculopathy, which will be achieved in collaboration with patients and clinicians, whose lived experiences and expertise offer invaluable insights into lumbar radiculopathy and its treatment. Our general objectives are 1) to gather patients' and clinicians' perspectives and involve them in research discussions and decisions and 2) to assess the impact of PPI on the future SALuBRITY pilot randomized clinical trial investigating SMT versus NRI in patients with lumbar radiculopathy. Specifically, we aim to answer following questions:

- Is the trial's main question and objective important and relevant to patients with lumbar radiculopathy and primary care clinicians of patients with lumbar radiculopathy?
- Are the recruitment processes and proposed methods for the clinical trial acceptable and sensitive to potential participants and clinician collaborators?
- Are the proposed trial outcomes relevant and important to patients with lumbar radiculopathy?
- Are the language and content of trial information appropriate and accessible to participants and clinicians?
- What is the impact of PPI on the relevance and quality of the SALuBRITY pilot randomized clinical trial?

METHODS AND ANALYSIS

Study design

We will involve a small group of patients (n=3 to 6) with lived experience of lumbar radiculopathy and primary care clinicians (n=3 to 4) that care for patients with lumbar radiculopathy. The different levels of involvement are distinguished, based on the flow of information between patients and the public, and professionals of the research team.[13] We will use consultation and collaboration approaches as qualitative methods. Consultation is defined as the collection of information from patients and the public, usually with no back-and-forth interaction with the research team and shows potential for gathering the view of a larger group of individuals. Collaboration

represents a bidirectional exchange, where decisions about research are shared and it requires commitment, openness and flexibility for all involved parties.[6,13] Group meetings and one-on-one interviews will be organized to discuss the acceptability, sensitivity, and relevance of the proposed methods, trial outcomes and information to the context of potential primary care clinician collaborators. An additional small number of patients (n=2 to 4) will be recruited for providing feedback on language and content of patient trial documents.

Patient and clinician advisors

Purposeful sampling will be used to involve patient and clinician advisors for this project.[14] It is a technique utilized in qualitative research, to gather individuals most knowledgeable about a topic of interest and supporting the intention to achieve depth of understanding until saturation is achieved. Patient advisors will be current or former patients of the chiropractic medicine polyclinic at Balgrist University Hospital in Zurich Switzerland, or from other internal or external collaborating clinicians. Eligibility criteria are age between 18 and 65 years, lived experience of lumbar radiculopathy and willingness to be involved as a patient advisor. Patients will be considered if they received at least one of the treatment interventions of interest (SMT or NRI), but patients who are experienced with multiple treatment modalities (such as chiropractic treatment, physiotherapy, massage, NRI, or surgery) will be preferred. Clinicians at the chiropractic medicine clinic at Balgrist University Hospital will be informed about the PPI project and will ask eligible patients for permission to get approached by the PPI team. Upon agreement, the potential patient advisor will be contacted and invited by a project lead for further information. Primary care clinicians in the surrounding region of Zurich will be contacted and informed about the PPI project. They will be considered eligible for involvement in this PPI project if they have experience providing primary care to patients with lumbar radiculopathy and are willing to be involved as a primary care clinician advisor.

Stages of involvement

The Critical Outcomes of Research Engagement (COREs) framework was designed for improving the quality and efficiency of research and maximizing its societal impact.[15] COREs will inform our PPI study design by drawing our attention to the ways in which patients and clinicians can be engaged during each of the specific

research stages as well as relevant outcomes to evaluate the impact of PPI activities. Patient and clinician advisors will be involved mainly through consultation and collaboration approaches to get their insights regarding recruitment strategy, patient and clinician information documents, aspects of trial methods, and outcome measures. Additionally, a patient advisor will be involved on the trial steering committee. **Figure 1** provides our adapted CORE framework with details on advisors, types of involvement, desired outcomes, and methods used, summarized by research stages.

Placeholder: Figure 1: Stages, outcomes and methods of involvement

PPI activities

Kickoff meeting

Patient and clinician advisors will meet for an initial, virtual kickoff event. The first part is offering information on how clinical research and PPI projects work and clarifies expectations off all involved parties. After splitting up in a patient and clinician advisory group, the second part of the kickoff event will familiarize the advisors with the planned PPI project tasks (see **Appendix A**). The kickoff event will facilitate the establishment of rapport among the advisors and the PPI project team, but also prepare and empower the patient and clinician advisors for involvement on the project. After the kickoff meeting, the expectations of the patients and clinicians are summarized and fed back as shared purpose to all participants to ensure accurate interpretation. Additionally, clinician information trial documents will be sent to the clinician advisors to give them enough time to review and prepare for the interview.

Individual and focus group interviews

A patient advisory group meeting and individual semi-structured one-on-one interviews with clinician advisors will be conducted virtually. Brief vignettes covering key PPI topics will be used to introduce topics and initiate consultation and collaboration discussions. Open questions will be used to initiate discussions, with more structured questions prespecified, in case recalibration of the discussions is needed (see **Appendix B**). Each interview will be conducted by three members of the research team. One of them will take the lead as the moderator who asks questions and guides discussion. The assistants will record the interview and take comprehensive notes.

Think aloud method

A think-aloud approach will be used to collect feedback on patient trial information documents, in which participants speak their thoughts aloud while performing a task.[16] The documents will be provided at the beginning of the meeting, and the participants will be asked to verbalize their thoughts while reading it aloud. The interviewer will take notes to contribute to the digitally recorded material. Discussion about ambiguous sections will take place after completion of the task. An instruction guide is provided in **Appendix C**.

Data collection and analysis

Demographics of all advisors will be collected by means of a short electronic questionnaire. Patients are communicated with in German (interviews, member-checking) and the data collected will be subsequently translated to English, whereas the clinicians will be interviewed in English. Instead of verbatim transcription, we will summarize and feedback PPI content to the patient and clinician advisors during a member-checking process to ensure accurate interpretation of patient and clinician inputs.[17]

For the qualitative analysis of the interviews, thematic analysis will be performed according to Braun and Clarke's six-phase guide: 1) familiarization with data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, 6) producing report.[18] The vignettes (**Appendix B**) will provide guidance and represent key questions we aim to code around for the deductive approach of the thematic analysis. At the same time, we use open coding which allows inductive thinking, to gather a broader view on the topic of interest and enabling recording of unsolicited themes. Patient and clinician interviews will initially be coded separately. As both advisory groups follow similar interview guides, they will be mapped onto one another, looking how codes and themes will manifest across both groups. Representative patient and clinician quotes will be identified.

Any modifications to the SALuBRITY pilot or future main trial methods as a result of PPI inputs will be thoroughly documented and recorded in an impact log (see **Appendix D**). In order to track the advisor's and researcher's experience over the course of the PPI project, two surveys are meant to be completed at different time points along the trial.[19] The first is delivered after the kickoff meeting, the second

after completion of all participation activities. The surveys are adapted to our project and provided in **Appendix E**. Descriptive statistics will be used to analyze the survey data.

The GRIPP2 reporting checklist will be used to enhance the quality and transparency of the PPI reporting.[20]

Patient and public involvement

This is a protocol for a patient and public involvement project.

ETHICS AND DISSEMINATION

The research ethics board of Canton Zurich confirmed that ethical approval is not required for this PPI project. The active involvement of patients or members of the public does not generally raise any ethical concerns for the people who are actively involved, as they are not acting in the same way as research participants. They are acting as specialist advisers, providing valuable knowledge and expertise based on their experience of a health condition or public health concern. Therefore, ethical approval is not needed for the active involvement element of the research, where people are involved in planning or advising on research.

Patient and clinician advisors will provide important end-user lived experience insights and advice—an important step for making research more relevant to end-users and improving its quality. This may facilitate its translation into clinical practice. Our dissemination plan for the PPI project will include publishing our results in a relevant peer-reviewed journal and presenting at conferences.

Declarations

Competing Interests

The authors have no competing interest to declare.

Funding

The current project was supported through internal research operating funds of the Department of Chiropractic Medicine, Balgrist University Hospital and University of Zurich.

283

Data sharing statement

Our PPI data will be made available in anonymised and deidentified format upon reasonable request.

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Authors' contributions

The roles of the authors during the different aspects of the research process were as follows: Protocol conception and design: CR, LH, LC, CAH; drafting the manuscript: CR, LH, CAH; critical revision of the manuscript: CR, LH, LC, MAP, CAH; supervision: CAH. All authors read and approved the final version of the manuscript.

294

Legends of figures

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Figure 1. Stages, outcomes and methods of involvement

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Appendix A – Kickoff Meeting

Aim: The kickoff meeting is designed for building the required capacity for the PPI project by offering information on how clinical research and PPI projects work and familiarizing advisors with the upcoming PPI tasks. The meeting will not only facilitate establishing rapport, but also prepare and empower patient and clinician advisors to be capable for high quality involvement on the PPI project.

Schedule:

Speaker	Timeline	Patient and clinician advisors together	
CAH, CR, LC, LH	5min	Welcome, introduction of project team member	
LH	5min	Clinical trial research in a nutshell, explained based on the SALuBRITY trial	
LC	5min	PPI introduction: Reasons why, consultation vs. collaboration approaches, expectations, aim for this PPI project	
CR	10min	Introduction advisors, ice breaker	
CR	10min	Expectations, shared purpose, next steps	
	= 35min		
10min break and split up in groups			
Timeline	Patient advisors		Clinician advisors
20min	Exchange of lived experience with lumbar radiculopathy		15min Presentation of trial methods, i.e., outcomes, design, interventions/procedures
15min	Presentation of trial methods, i.e., outcomes, design, interventions /procedures		10min Time for questions
10min	Time for questions		
=55min			=35min
Total duration: 35 + 45 + 10min break = 1h 30 min		Total duration: 35 + 35 + 10min break = 1h 20 min	

Appendix B – Interview Guide

Patient Advisors Interview Guide

Vignette 1: Research question

Introduction:

The research question and primary objective of the future main trial was presented in detail during the kick-off meeting and is briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:

What are your thoughts on the importance and relevance of the trial’s main question?

“To compare SMT with NRI in patients with lumbar radiculopathy in terms of pain impact at 12-wees after randomization and assess outcomes over a 1-year follow-up.”

Specific guiding questions:

None

Vignette 2: Proposed methods

Information about proposed methods with the double sham controlled, randomized study design presented in detail during the kick-off meeting.

a) Study design

Introduction:

The principle and purpose of the two study arms (group A receiving active SMT and sham NRI, group B receiving active NRI and sham SMT) as well as the importance of blinding of patients and managing clinician is presented again.

Opening question:

What are your thoughts on the proposed randomised double sham design?

Specific guiding questions:

- Thoughts on the principle of random allocation of the two trial active interventions?
- Thoughts on the principle of blinding of patients to the active intervention?
- Thoughts on the principle of blinding of the managing clinician?
- Thoughts on the treatment by another, “foreign” clinician?

b) Recruitment process and timings

Introduction:

The process from recruitment, screening, randomization, to the start of treatment is briefly outlined again.

Opening question:

What do you think about the proposed recruitment processes and timings?

Specific guiding questions:

- Thoughts on the proposed timings from primary care visit to initial trial telephone screen, to trial eligibility screening visit, to first treatment visit? Assumption 0-5days.

c) Discontinuation of pain medication

Introduction:

Rationale for discontinuing pain medication for 12-24 hours prior to each study visit is discussed.

Opening question:

What are your thoughts about the request for patients to discontinue their pain medication prior to trial study visits?

Specific guiding questions:

- Would you personally be willing to forego your pain medication during a 0-24 hour period if you were participating in such a trial? Why, or why not?

Vignette 3: Trial outcomes

a) Primary outcome

Introduction:

Information about proposed outcomes is presented to the patient advisors. The focus is put on the primary clinical outcome of the trial (i.e. pain impact, measured with the 3-item PEG scale), which is presented in detail. Other secondary patient-reported outcomes (i.e. physical function, quality of life, patient satisfaction with care, pain medication use, work disability, healthcare use) are presented briefly to the advisors to provide them enough information to discuss the relevance and importance of the proposed primary outcome.

Opening question:

What are your thoughts about the trial's proposed outcomes?

Specific guiding questions:

- Do you think pain impact (measured with the PEG scale) is a relevant and important primary outcome?
- Thoughts on the most relevant pain location to assess pain impact (i.e. back pain, leg pain, or overall pain)?
- Do you think it is important to ask for the intensity of the pain?
- Can you think of other relevant outcomes that we have not covered yet?

b) Clinical course as measured by weekly SMS messaging

Introduction:

The idea of measuring clinical outcomes by weekly SMS messaging is presented to the patient advisors.

Opening question:

What are your thoughts about weekly SMS messaging as a way to measure primary outcomes?

Specific guiding questions:

- Would you feel comfortable with this way of measuring clinical course?
- Do you have experience collecting data this way?
- How optimistic are you about your ability to reliably provide data about clinical outcomes via SMS?

Clinician Advisors Interview Guide

Vignette 1: Research question

Introduction:

The research question and primary objective of the future main trial were presented in detail during the kick-off meeting and are briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:

What are your thoughts on the importance and relevance of the trial's main question?

Specific guiding questions:

- Could you imagine that the results of this trial would influence your clinical practice?
- Where do you see gaps in evidence that would be useful to guide your clinical practice and treatment of patients with lumbar radiculopathy?

Vignette 2: Proposed methods

a) Recruitment process and timings

Introduction:

The process from recruitment, screening, randomization, to the start of treatment is briefly outlined again. The trial clinician information form was provided to all clinician advisors after the kick-off group meeting to give them enough time to read and review it. The form contains a brief summary of the trial itself, information about the eligibility criteria, and the instruction about the referring process of potential participants. Different options/processes of referring mechanisms are presented.

Opening question:

What are your thoughts on the proposed recruitment processes and timings?

Pre-specified questions:

- Thoughts on improvements of the referring process?
- What are your thoughts on the clinician recruitment information package?

b) Discontinuation of pain medication

Introduction:

The research question and primary objective of the future main trial were presented in detail during the kick-off meeting and are briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:

What are your thoughts about the proposal to have patients discontinue their pain medication 0 to 48 hours prior to study visits?

Specific guiding questions:

- What are your thoughts about the proposal to have patients discontinue their pain medication 12 to 24 h prior to study visits?

Vignette 3: Trial outcomes

a) Primary outcome

Introduction:

Information about proposed outcomes, with the focus on the primary clinical outcome of the trial (i.e. pain impact, measured with the 3-item PEG scale), is presented again.

Opening question:

What are your thoughts about the trial's proposed primary clinical outcome?

Specific guiding questions:

- Do you think pain impact (measured with the PEG scale) is a relevant and important primary outcome?

- Thoughts on the most relevant pain location to assess pain impact (i.e. back pain, leg pain, or overall pain)?

b) Non-inferiority margin

Introduction:

The non-inferiority approach aims to determine whether SMT is non inferior to NRI in terms of pain impact. The minimal clinically important difference (MCID) in most trials in literature regarding the pain numeric rating scale (NRS), is 1 point on a scale between 1 and 10. Proposed is a non-inferiority margin of 0.75 points on the PEG scale, meaning 75% of the MCID.

Opening question:

Do you think a between-group difference of up to 0.75 points on the PEG scale is ignorable?

Vignette 4: Referral Network

Introduction:

One of the main challenges of the SALuBRITY trial is the recruitment of the participants. Recruitment is taking place at primary care practices and through Balgrist internal network.

Opening question:

Do you have other ideas for recruitment of GP referral network?

Appendix C – Think Aloud Protocol

1. Introduction of interviewer, study title and importance

Title: Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: a patient and public involvement project

Importance: Our goal is to enhance the quality and relevance of the SALuBRITY trial by collaborating and involving patients and clinicians, whose lived experiences and expertise offer invaluable insights into lumbar radiculopathy and its treatment.

2. Goal of think aloud protocol

The think aloud protocol gives insights to the difficulties encountered while reading the patient trial information documents. It is not about judging your task performance, we rather aim for receiving information about the language, comprehensibility and potential missing information of the trial documents.

3. Explanation of the think aloud protocol

In the think aloud protocol, we will ask you to simply say out loud whatever comes into your mind as you read aloud the patient study information document. The task will be video and audio recorded (through Zoom), and only the PPI project team will have access to the recording. One project team member will take notes to contribute to the digitally recorded material and may remind you to “keep thinking out loud or speaking your thoughts”, if you lapse into silence. Discussion about difficult or confusing sections will take place after completion of the task. It may help you to remember that you are teaching us about the quality of the documents from your perspective and advising us on how the documents could be better.

4. Give an example of the think aloud protocol

I will give an example of the think aloud protocol to help you get familiarized with the process.

Example: I read through a patient information document, we received from the research department of Balgrist about drinks containing polyphenol and the influence on the immune system and muscular growth.

5. General instructions

Feel free to stop the task if you feel uncomfortable.
Do you have any questions about the process?
Please keep thinking out loud (or speaking your thoughts).
You can begin the process.

6. Instructions after task completions

Thank you for participating in this think aloud exercise.
How did you feel while performing the task?
Do you have any feedback related to the task?
Do you have any questions or are there any parts of the document you want to talk about?

Appendix D – Impact log

Patients

Vignettes	Advisor	Discussion	Impact
Research question Key words: importance, relevance			
Proposed methods - Study design Key words: double sham, random allocation, blinding			
Proposed methods - Recruitment process and timings Key words: time intervals			
Proposed methods - Pain medication Key words: 0-24h			
Trial outcomes - Primary outcome Key words: pain impact, pain location, intensity			
Trial outcomes - Clinical course by SMS			

Clinicians

Vignettes	Advisor	Discussion	Impact
Research question Key words: importance, relevance, clinical practice, gaps in evidence help guiding treatment			
Proposed methods - Recruitment process Key words: clinician information form, recruitment process, timing, referring process			


Proposed methods - Pain medication Key words: 0-24h			
Trial outcomes - Primary outcome Key words: pain impact, pain location, intensity			
Trial outcomes - Non-inferiority margin Key words: 0.75 points on PEG ignorable			
Referral Network Key words: GP referral network			

Appendix E– Evaluation PPI

The patient/caregiver and researcher partner surveys are designed to understand the actual experience of all involved participants, when researcher partner with patients and caregivers on a project, where patients and/or caregivers are members of the research team.

The patient/caregiver and researcher surveys serve as a template and the number of questions and surveys are adapted to our project.[14] The experience is collected after the kickoff meeting (initial survey) and after completing all participation activities of the PPI project (end project survey).

Initial Survey Advisors

Survey Instructions	<input type="radio"/> English <input type="radio"/> Deutsch
Have you worked as a patient/clinician advisor on a research project prior to this one?	<input type="radio"/> Yes <input type="radio"/> No
Please describe your experience as patient/clinician advisor.	_____
Was the research team introduced to you?	<input type="radio"/> Yes <input type="radio"/> No
Did someone of the research team introduce you to the other project advisors?	<input type="radio"/> Yes <input type="radio"/> No
Was the SALuBRITY patient and public involvement (PPI) project described to you before you started working with the team?	<input type="radio"/> Yes <input type="radio"/> No
Was there enough time for you to learn about the SALuBRITY PPI project before you agreed to participate as patient/clinician advisor?	<input type="radio"/> Yes <input type="radio"/> No
Was there enough time for you to get to know the other project advisors before the SALuBRITY PPI project started?	<input type="radio"/> Yes <input type="radio"/> No
Were the communication tools explained to you before the SALuBRITY PPI started?	<input type="radio"/> Yes <input type="radio"/> No
Did you and the research team discuss your role on the team?	<input type="radio"/> Yes <input type="radio"/> No
Were the roles of the other members of the project team explained to you?	<input type="radio"/> Yes <input type="radio"/> No
Do you feel you are equipped to contribute to the SALuBRITY PPI project?	<div style="display: flex; justify-content: space-between; align-items: center;"> not at all totally </div> <div style="text-align: center;">  </div> <div style="text-align: center; font-size: small;"> (Place a mark on the scale above) </div>

End Survey Advisors

Survey Instructions

☐ English
☐ Deutsch

How comfortable do you think you are now with your understanding of the SALuBRITY patient and public (PPI) project?

very uncomfortable

very comfortable

(Place a mark on the scale above)

How comfortable did you feel speaking up in the meetings?

very uncomfortable

very comfortable

(Place a mark on the scale above)

Did you feel the team listened to you and absorbed your input?

☐ Yes ☐ No

Did any of the researchers on the team have problems dealing with patient/clinician partners?

☐ Yes ☐ No

What was the nature of the problem?

Did the research team work with you to accommodate for your challenges and ensure that it is easy for you to participate?

☐ Yes ☐ No

In your opinion, did your insights and comments impact the decisions of the future SALuBRITY trial?

never

definitely

(Place a mark on the scale above)

Did you share your personal experience as a patient/clinician as part of your role as advisor on the SALuBRITY PPI project?

☐ Yes ☐ No

What preparation would have been useful to have before being involved in this PPI project?

If you could start over again as a patient/clinician advisor, what would you do differently?

What 3 things did you learn from the experience as a patient/clinician advisor on a multidisciplinary team?

1

2

3

What 3 things could the research team have done to improve your experience?

1

2

3

Do you feel the patient/clinician partnership was productive and enriched the quality and relevance of the SALuBRITY trial?

☐ Yes ☐ No

Do you have any concerns about partnering with researchers at this point?

☐ Yes ☐ No

What was most challenging when partnering with researchers?

Where do you think your involvement mattered the most?

For peer review only

Initial Survey Researchers

Survey Instructions

☐ English
☐ Deutsch

Have you worked with patient and/or public advisor on a research project prior to this one?

☐ Yes
☐ No

Please describe your experience with patient and/or public advisors.

Did you establish a profile of the type of person you wanted as a patient/caregiver partner prior to looking for candidates?

☐ Yes
☐ No

Was there enough time for the patients/clinicians to learn about the SALuBRITY PPI project before they agreed to participate as patient/clinician advisor?

☐ Yes
☐ No

Was there enough time for the patient/clinician advisors to get to know the other project advisors before the SALuBRITY PPI project startet?

☐ Yes
☐ No

Do you feel you and your team are well prepared to work with patient/clinician advisors on this SALuBRITY PPI project?

not at all

totally


(Place a mark on the scale above)

End Survey Researchers

Survey Instructions

☐ English
☐ Deutsch

How comfortable do you think patient/clinician advisors are with their understanding of the SALuBRITY PPI project?

very uncomfortable very comfortable

(Place a mark on the scale above)

Did the patient/clinician advisors speak up and contribute at most meetings?

very uncomfortable very comfortable

(Place a mark on the scale above)

Did you feel you and the research team listened to and absorbed the inputs of the patient/clinician advisors?

☐ Yes ☐ No

Did any of the researchers on the team have problems dealing with patient/clinician partners?

☐ Yes ☐ No

What was the nature of the problem?


Did the patient/clinician advisors' comments during the member-checking process affect the final outcome of the SALuBRITY PPI Project?

☐ Yes
☐ No

Did you work with the patient/clinician advisors to accommodate for their challenges and ensure that it is easy for them to participate?

☐ Yes ☐ No

In your opinion, did the insights and comments of the patient/clinician advisors impact the decisions of the SALuBRITY trial?

never definitely

(Place a mark on the scale above)

Did the patient/clinician advisors share their personal experience as a patient or clinician on the SALuBRITY PPI project?

☐ Yes ☐ No

Did you feel you and your team were well prepared to work with patient/clinician advisors on the SALuBRITY PPI project?

☐ Yes ☐ No

If you could start over again, what would you do differently?

What 3 things did you learn from the experience of partnering with patients/clinicians?

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What 3 things could be done better to improve your experience?

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2 _____

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Do you feel the patient/clinician partnership was productive and enriched the quality and relevance of the SALuBRITY trial? ☐ Yes ☐ No

Do you have any concerns about partnering with patients/clinicians at this point? ☐ Yes ☐ No

What was most challenging when partnering with patient/clinician advisors? _____

Where do you think patient/clinician involvement mattered the most? _____

BMJ Open

Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: protocol of a patient and public involvement project

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Title: Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: protocol of a patient and public involvement project

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ABSTRACT

Introduction A patient and public involvement (PPI) project will be embedded within the SALuBRITY pilot trial, a two parallel group, double sham controlled, randomised clinical trial. The study aims to compare the effectiveness of spinal manual therapy and corticosteroid nerve root injections, two methods commonly used to treat patients with lumbar radiculopathy. We aim to gather patients' and clinicians' perspectives and involve them in decisions related to the research question and objectives, proposed trial recruitment processes and methods, and proposed outcome measures.

Methods and analysis A small group of patients with lived experience of lumbar radiculopathy and primary care clinicians with experience in the treatment of patients with lumbar radiculopathy are involved. An initial kickoff event prepares and empowers the advisors for involvement in the project, followed by semi-structured patient group and one-on-one clinician interviews. We follow the Critical Outcomes of Research Engagement (COREs) framework for assessing the impact of patient engagement in research. We will summarize and feedback PPI content to the patient and clinician advisors during a member-checking process to ensure accurate interpretation of patient and clinician inputs. Inductive and deductive thematic analysis will be used for the qualitative analysis of the interviews. Two surveys will be completed at different points along the trial to track the advisors' and researchers' experiences over the course of the PPI project. Any modifications to the SALuBRITY trial methods due to PPI inputs will be thoroughly documented and recorded in an impact log.

Ethics and dissemination The SALuBRITY pilot trial will be submitted for ethical review and approval by the independent research ethics committee of Canton Zurich. The research ethics board confirmed that ethical approval for the PPI subproject is not required. PPI results will be disseminated in a peer-reviewed journal and presented at conferences.

Strengths and limitations of this study:

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- This PPI project is an important step for making research more relevant to end-users and facilitating research translation into clinical practice.
- Existing frameworks guide consultation and collaboration approaches and draw our attention to relevant outcomes to evaluate the impact of PPI activities.
- Patient and clinician advisors will be supplied with detailed information about PPI in general and the future trial to be empowered for their contribution to the project.
- Sample size is small and inadequate for quantitative analysis but allows a pragmatic qualitative approach and recognition of multiple individual realities.

INTRODUCTION

Patients' role in research has changed over the past decades from being study participants to getting engaged at different levels and in different stages of research. The value of patient and public involvement (PPI) is increasingly recognized and prioritized by research regulators and funders,[1–3] academic journals,[4] and patient organizations.[5] The INVOLVE initiative, established in 1996 and funded by the National Institute for Health Research (NIHR) of the United Kingdom, was taken over by NIHR Center for Engagement and Dissemination in 2020 and defines public involvement as research carried out “with” or “by” members of the public rather than “to”, “about” or “for” them.[6] PPI represents an essential approach for keeping the research relevant to end-users (e.g., patients and clinicians) and improving its translation into real-world clinical practice by integrating patient and clinician perspectives on the relevant research topic.

Back-related leg pain affects about 200 million people worldwide, and was estimated to account for up to 35 million years lived with disability in 2017.[7] Lumbar radiculopathy—arising from lumbar spinal nerve root compression or irritation—is characterized by low back pain (LBP) that radiates down the leg in a lumbar nerve distribution.[8] With increased pain and disability, people suffering from back-related leg pain have poorer prognosis, quality of life and an increased use of health resources compared to people with LBP alone.[9] Spinal manual therapy (SMT) and corticosteroid nerve root injection (NRI) are two common conservative treatment methods in routine clinical care, but there is uncertainty regarding their effects. To assist patients, clinicians, and policymakers with decision-making on the treatment of lumbar radiculopathy based on high quality evidence, the SALuBRITY pilot trial – a two parallel group, double sham controlled, randomised clinical trial – is being developed.

PPI involvement in the development phase of a clinical trial can help to identify possible challenges in the collaboration of researcher with patients at an early stage, with all involved people facing beneficial impacts. Researchers profit from extended funding, better enrollment rates [10,11] and increased trust and advocates within the community under research.[12] Patients describe empowerment, increased knowledge and confidence, which emphasize the wide societal benefits and the potential for research to act as a positive force in society.[12] In recognition of these benefits – ultimately

leading to improved quality and relevance of the research being conducted – we will carry out a PPI project nested in the SALuBRITY trial, aiming to improve the quality and relevance of the future trial.

Our goal is to enhance the quality of care and quality of life for patients with lumbar radiculopathy, which will be achieved in collaboration with patients and clinicians, whose lived experiences and expertise offer invaluable insights into lumbar radiculopathy and its treatment. Our general objectives are 1) to gather patients' and clinicians' perspectives and involve them in research discussions and decisions and 2) to assess the impact of PPI on the future SALuBRITY pilot randomized clinical trial investigating SMT versus NRI in patients with lumbar radiculopathy. Specifically, we aim to answer following questions:

- Is the trial's main question and objective important and relevant to patients with lumbar radiculopathy and primary care clinicians of patients with lumbar radiculopathy?
- Are the recruitment processes and proposed methods for the clinical trial acceptable and sensitive to potential participants and clinician collaborators?
- Are the proposed trial outcomes relevant and important to patients with lumbar radiculopathy?
- Are the language and content of trial information appropriate and accessible to participants and clinicians?
- What is the impact of PPI on the relevance and quality of the SALuBRITY pilot randomized clinical trial?

METHODS AND ANALYSIS

Study design

We will involve a small group of patients (n=3 to 6) with lived experience of lumbar radiculopathy and primary care clinicians (n=3 to 4) that care for patients with lumbar radiculopathy. The different levels of involvement are distinguished, based on the flow of information between patients and the public, and professionals of the research team.[13] We will use consultation and collaboration approaches as qualitative methods. Consultation is defined as the collection of information from patients and the public, usually with no back-and-forth interaction with the research team and shows potential for gathering the view of a larger group of individuals. Collaboration

represents a bidirectional exchange, where decisions about research are shared and it requires commitment, openness and flexibility for all involved parties.[6,13] Group meetings and one-on-one interviews will be organized to discuss the acceptability, sensitivity, and relevance of the proposed methods, trial outcomes and information to the context of potential primary care clinician collaborators. To gain feedback on language and content of patient trial documents, additional patients will be recruited one after another to participate in a think-aloud process until no new feedback is generated (a priori estimation, n=2 to 4).

Patient and clinician advisors

Purposeful sampling will be used to involve patient and clinician advisors for this project.[14] It is a technique utilized in qualitative research, to gather individuals most knowledgeable about a topic of interest and supporting the intention to achieve depth of understanding until saturation is achieved. Patient advisors will be current or former patients of the chiropractic medicine polyclinic at Balgrist University Hospital in Zurich Switzerland, or from other internal or external collaborating clinicians. Eligibility criteria are age between 18 and 65 years, lived experience of lumbar radiculopathy and willingness to be involved as a patient advisor. Patients will be considered if they received at least one of the treatment interventions of interest (SMT or NRI), but patients who are experienced with multiple treatment modalities (such as chiropractic treatment, physiotherapy, massage, NRI, or surgery) will be preferred. Clinicians at the chiropractic medicine clinic at Balgrist University Hospital will be informed about the PPI project and will ask eligible patients for permission to get approached by the PPI team. Upon agreement, the potential patient advisor will be contacted and invited by a project lead for further information. Primary care clinicians in the surrounding region of Zurich will be contacted and informed about the PPI project. They will be considered eligible for involvement in this PPI project if they have experience providing primary care to patients with lumbar radiculopathy and are willing to be involved as a primary care clinician advisor. Patient and clinician advisors will not be incentivized to participate through any offer of monetary or other compensation for their involvement, but a small token of appreciation (gift card of small value) will be provided in thanks for their involvement after completion of the PPI activities.

Stages of involvement

The Critical Outcomes of Research Engagement (COREs) framework was designed for improving the quality and efficiency of research and maximizing its societal impact.[15] COREs will inform our PPI study design by drawing our attention to the ways in which patients and clinicians can be engaged during each of the specific research stages as well as relevant outcomes to evaluate the impact of PPI activities. Patient and clinician advisors will be involved mainly through consultation and collaboration approaches to get their insights regarding recruitment strategy, patient and clinician information documents, aspects of trial methods, and outcome measures. Additionally, a patient advisor will be involved on the trial steering committee. **Figure 1** provides our adapted CORE framework with details on advisors, types of involvement, desired outcomes, and methods used, summarized by research stages.

Placeholder: Figure 1: Stages, outcomes and methods of involvement

PPI activities

Kickoff meeting

Patient and clinician advisors will meet for an initial, virtual kickoff event. The first part is offering information on how clinical research and PPI projects work and clarifies expectations off all involved parties. After splitting up in a patient and clinician advisory group, the second part of the kickoff event will familiarize the advisors with the planned PPI project tasks (see **Appendix A**). The kickoff event will facilitate the establishment of rapport among the advisors and the PPI project team, but also prepare and empower the patient and clinician advisors for involvement on the project. After the kickoff meeting, the expectations of the patients and clinicians are summarized and fed back as shared purpose to all participants to ensure accurate interpretation. Additionally, clinician information trial documents will be sent to the clinician advisors to give them enough time to review and prepare for the interview.

Individual and focus group interviews

A patient advisory group meeting and individual semi-structured one-on-one interviews with clinician advisors will be conducted virtually. Brief vignettes covering key PPI topics will be used to introduce topics and initiate consultation and collaboration discussions. Open questions will be used to initiate discussions, with more structured questions prespecified, in case recalibration of the discussions is needed (see **Appendix B**). Each interview will be conducted by three members of the research

team. One of them will take the lead as the moderator who asks questions and guides discussion. The assistants will record the interview and take comprehensive notes, with any discrepancies in notes resolved by consensus.

Think aloud method

A think-aloud approach will be used to collect feedback on patient trial information documents, in which participants speak their thoughts aloud while performing a task.[16] The documents will be provided at the beginning of the meeting, and the participants will be asked to verbalize their thoughts while reading it aloud. An assistant will take notes to contribute to the digitally recorded material. Discussion about ambiguous sections will take place after completion of the task. An instruction guide is provided in **Appendix C**.

Data collection and analysis

Demographics of all advisors will be collected by means of a short electronic questionnaire. Communication with patient advisors will be in German (interviews, member-checking) as this is the primary language in the region and the data collected will be subsequently translated to English. As almost all clinicians in Switzerland are proficient in English (global academic language), clinician advisors will be interviewed in English. Instead of verbatim transcription, we will summarize and feedback PPI content to the patient and clinician advisors during a member-checking process to ensure accurate interpretation of patient and clinician inputs.[17]

For the qualitative analysis of the interviews, thematic analysis will be performed according to Braun and Clarke's six-phase guide: 1) familiarization with data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, 6) producing report.[18] The vignettes (**Appendix B**) will provide guidance and represent key questions we aim to code around for the deductive approach of the thematic analysis. At the same time, we use open coding which allows inductive thinking, to gather a broader view on the topic of interest and enabling recording of unsolicited themes. Patient and clinician interviews will initially be coded separately. As both advisory groups follow similar interview guides, they will be mapped onto one another, looking how codes and themes will manifest across both groups. Representative patient and clinician quotes will be identified.

Any modifications to the SALuBRITY pilot or future main trial methods as a result of PPI inputs will be thoroughly documented and recorded in an impact log (see **Appendix D**). In order to track the advisor's and researcher's experience over the course of the PPI project, two surveys are meant to be completed at different time points along the trial.[19] The first is delivered after the kickoff meeting, the second after completion of all participation activities. The surveys are adapted to our project and provided in **Appendix E**. Descriptive statistics will be used to analyze the survey data.

The GRIPP2 reporting checklist will be used to enhance the quality and transparency of the PPI reporting.[20]

Patient and public involvement in the design of this protocol

This is a protocol for a patient and public involvement project. No patients or members of the public were involved in the design of the protocol.

ETHICS AND DISSEMINATION

The research ethics board of Canton Zurich confirmed that ethical approval is not required for this PPI project. The active involvement of patients or members of the public does not generally raise any ethical concerns for the people who are actively involved, as they are not acting in the same way as research participants. They are acting as specialist advisers, providing valuable knowledge and expertise based on their experience of a health condition or public health concern. Therefore, ethical approval is not needed for the active involvement element of the research, where people are involved in planning or advising on research.

Patient and clinician advisors will provide important end-user lived experience insights and advice—an important step for making research more relevant to end-users and improving its quality. This may facilitate its translation into clinical practice. Our dissemination plan for the PPI project will include publishing our results in a relevant peer-reviewed journal and presenting at conferences.

Declarations

Competing Interests

The authors have no competing interest to declare.

Funding

This protocol received no funding support.

Data sharing statement

Our PPI data will be made available in anonymised and deidentified format upon reasonable request.

Authors' contributions

Study conception: CAH; Protocol design: CAH, LC, MAP, CR, LH; drafting the manuscript: CR, LH, CAH; critical revision of the manuscript: CR, LH, LC, MAP, CAH; supervision: CAH. All authors read and approved the final version of the manuscript.

Legends of figures

Figure 1. Stages, outcomes and methods of involvement

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Figure 1. Stages, outcomes and methods of involvement
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Appendix A – Kickoff Meeting

Aim: The kickoff meeting is designed for building the required capacity for the PPI project by offering information on how clinical research and PPI projects work and familiarizing advisors with the upcoming PPI tasks. The meeting will not only facilitate establishing rapport, but also prepare and empower patient and clinician advisors to be capable for high quality involvement on the PPI project.

Schedule:

Speaker	Timeline	Patient and clinician advisors together	
CAH, CR, LC, LH	5min	Welcome, introduction of project team member	
LH	5min	Clinical trial research in a nutshell, explained based on the SALuBRITY trial	
LC	5min	PPI introduction: Reasons why, consultation vs. collaboration approaches, expectations, aim for this PPI project	
CR	10min	Introduction advisors, ice breaker	
CR	10min	Expectations, shared purpose, next steps	
	= 35min		
10min break and split up in groups			
Timeline	Patient advisors		Clinician advisors
20min	Exchange of lived experience with lumbar radiculopathy		15min Presentation of trial methods, i.e., outcomes, design, interventions/procedures
15min	Presentation of trial methods, i.e., outcomes, design, interventions /procedures		10min Time for questions
10min	Time for questions		
=55min			=35min
Total duration: 35 + 45 + 10min break = 1h 30 min		Total duration: 35 + 35 + 10min break = 1h 20 min	

Appendix B – Interview Guide

Patient Advisors Interview Guide

Vignette 1: Research question

Introduction:

The research question and primary objective of the future main trial was presented in detail during the kick-off meeting and is briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:

What are your thoughts on the importance and relevance of the trial’s main question?

“To compare SMT with NRI in patients with lumbar radiculopathy in terms of pain impact at 12-wees after randomization and assess outcomes over a 1-year follow-up.”

Specific guiding questions:

None

Vignette 2: Proposed methods

Information about proposed methods with the double sham controlled, randomized study design presented in detail during the kick-off meeting.

a) Study design

Introduction:

The principle and purpose of the two study arms (group A receiving active SMT and sham NRI, group B receiving active NRI and sham SMT) as well as the importance of blinding of patients and managing clinician is presented again.

Opening question:

What are your thoughts on the proposed randomised double sham design?

Specific guiding questions:

- Thoughts on the principle of random allocation of the two trial active interventions?
- Thoughts on the principle of blinding of patients to the active intervention?
- Thoughts on the principle of blinding of the managing clinician?
- Thoughts on the treatment by another, “foreign” clinician?

b) Recruitment process and timings

Introduction:

The process from recruitment, screening, randomization, to the start of treatment is briefly outlined again.

Opening question:

What do you think about the proposed recruitment processes and timings?

Specific guiding questions:

- Thoughts on the proposed timings from primary care visit to initial trial telephone screen, to trial eligibility screening visit, to first treatment visit? Assumption 0-5days.

c) Discontinuation of pain medication

Introduction:

Rationale for discontinuing pain medication for 12-24 hours prior to each study visit is discussed.

Opening question:

What are your thoughts about the request for patients to discontinue their pain medication prior to trial study visits?

Specific guiding questions:

- Would you personally be willing to forego your pain medication during a 0-24 hour period if you were participating in such a trial? Why, or why not?

Vignette 3: Trial outcomes

a) Primary outcome

Introduction:

Information about proposed outcomes is presented to the patient advisors. The focus is put on the primary clinical outcome of the trial (i.e. pain impact, measured with the 3-item PEG scale), which is presented in detail. Other secondary patient-reported outcomes (i.e. physical function, quality of life, patient satisfaction with care, pain medication use, work disability, healthcare use) are presented briefly to the advisors to provide them enough information to discuss the relevance and importance of the proposed primary outcome.

Opening question:

What are your thoughts about the trial's proposed outcomes?

Specific guiding questions:

- Do you think pain impact (measured with the PEG scale) is a relevant and important primary outcome?
- Thoughts on the most relevant pain location to assess pain impact (i.e. back pain, leg pain, or overall pain)?
- Do you think it is important to ask for the intensity of the pain?
- Can you think of other relevant outcomes that we have not covered yet?

b) Clinical course as measured by weekly SMS messaging

Introduction:

The idea of measuring clinical outcomes by weekly SMS messaging is presented to the patient advisors.

Opening question:

What are your thoughts about weekly SMS messaging as a way to measure primary outcomes?

Specific guiding questions:

- Would you feel comfortable with this way of measuring clinical course?
- Do you have experience collecting data this way?
- How optimistic are you about your ability to reliably provide data about clinical outcomes via SMS?

Clinician Advisors Interview Guide

Vignette 1: Research question

Introduction:

The research question and primary objective of the future main trial were presented in detail during the kick-off meeting and are briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:

What are your thoughts on the importance and relevance of the trial's main question?

Specific guiding questions:

- Could you imagine that the results of this trial would influence your clinical practice?
- Where do you see gaps in evidence that would be useful to guide your clinical practice and treatment of patients with lumbar radiculopathy?

Vignette 2: Proposed methods

a) Recruitment process and timings

Introduction:

The process from recruitment, screening, randomization, to the start of treatment is briefly outlined again. The trial clinician information form was provided to all clinician advisors after the kick-off group meeting to give them enough time to read and review it. The form contains a brief summary of the trial itself, information about the eligibility criteria, and the instruction about the referring process of potential participants. Different options/processes of referring mechanisms are presented.

Opening question:

What are your thoughts on the proposed recruitment processes and timings?

Pre-specified questions:

- Thoughts on improvements of the referring process?
- What are your thoughts on the clinician recruitment information package?

b) Discontinuation of pain medication

Introduction:

The research question and primary objective of the future main trial were presented in detail during the kick-off meeting and are briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:

What are your thoughts about the proposal to have patients discontinue their pain medication 0 to 48 hours prior to study visits?

Specific guiding questions:

- What are your thoughts about the proposal to have patients discontinue their pain medication 12 to 24 h prior to study visits?

Vignette 3: Trial outcomes

a) Primary outcome

Introduction:

Information about proposed outcomes, with the focus on the primary clinical outcome of the trial (i.e. pain impact, measured with the 3-item PEG scale), is presented again.

Opening question:

What are your thoughts about the trial's proposed primary clinical outcome?

Specific guiding questions:

- Do you think pain impact (measured with the PEG scale) is a relevant and important primary outcome?
- Thoughts on the most relevant pain location to assess pain impact (i.e. back pain, leg pain, or overall pain)?

b) Non-inferiority margin

Introduction:

The non-inferiority approach aims to determine whether SMT is non inferior to NRI in terms of pain impact. The minimal clinically important difference (MCID) in most trials in literature regarding the pain numeric rating scale (NRS), is 1 point on a scale between 1 and 10. Proposed is a non-inferiority margin of 0.75 points on the PEG scale, meaning 75% of the MCID.

Opening question:

Do you think a between-group difference of up to 0.75 points on the PEG scale is ignorable?

Vignette 4: Referral Network

Introduction:

One of the main challenges of the SALuBRITY trial is the recruitment of the participants. Recruitment is taking place at primary care practices and through Balgrist internal network.

Opening question:

Do you have other ideas for recruitment of GP referral network?

Appendix C – Think Aloud Protocol

1. Introduction of interviewer, study title and importance

Title: Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: a patient and public involvement project

Importance: Our goal is to enhance the quality and relevance of the SALuBRITY trial by collaborating and involving patients and clinicians, whose lived experiences and expertise offer invaluable insights into lumbar radiculopathy and its treatment.

2. Goal of think aloud protocol

The think aloud protocol gives insights to the difficulties encountered while reading the patient trial information documents. It is not about judging your task performance, we rather aim for receiving information about the language, comprehensibility and potential missing information of the trial documents.

3. Explanation of the think aloud protocol

In the think aloud protocol, we will ask you to simply say out loud whatever comes into your mind as you read aloud the patient study information document. The task will be video and audio recorded (through Zoom), and only the PPI project team will have access to the recording. One project team member will take notes to contribute to the digitally recorded material and may remind you to “keep thinking out loud or speaking your thoughts”, if you lapse into silence. Discussion about difficult or confusing sections will take place after completion of the task. It may help you to remember that you are teaching us about the quality of the documents from your perspective and advising us on how the documents could be better.

4. Give an example of the think aloud protocol

I will give an example of the think aloud protocol to help you get familiarized with the process.

Example: I read through a patient information document, we received from the research department of Balgrist about drinks containing polyphenol and the influence on the immune system and muscular growth.

5. General instructions

Feel free to stop the task if you feel uncomfortable.
Do you have any questions about the process?
Please keep thinking out loud (or speaking your thoughts).
You can begin the process.

6. Instructions after task completions

Thank you for participating in this think aloud exercise.
How did you feel while performing the task?
Do you have any feedback related to the task?
Do you have any questions or are there any parts of the document you want to talk about?

Appendix D – Impact log

Patients

Vignettes	Advisor	Discussion	Impact
Research question Key words: importance, relevance			
Proposed methods - Study design Key words: double sham, random allocation, blinding			
Proposed methods - Recruitment process and timings Key words: time intervals			
Proposed methods - Pain medication Key words: 0-24h			
Trial outcomes - Primary outcome Key words: pain impact, pain location, intensity			
Trial outcomes - Clinical course by SMS			

Clinicians

Vignettes	Advisor	Discussion	Impact
Research question Key words: importance, relevance, clinical practice, gaps in evidence help guiding treatment			
Proposed methods - Recruitment process Key words: clinician information form, recruitment process, timing, referring process			


Proposed methods - Pain medication Key words: 0-24h			
Trial outcomes - Primary outcome Key words: pain impact, pain location, intensity			
Trial outcomes - Non-inferiority margin Key words: 0.75 points on PEG ignorable			
Referral Network Key words: GP referral network			

Appendix E– Evaluation PPI

The patient/caregiver and researcher partner surveys are designed to understand the actual experience of all involved participants, when researcher partner with patients and caregivers on a project, where patients and/or caregivers are members of the research team.

The patient/caregiver and researcher surveys serve as a template and the number of questions and surveys are adapted to our project.[14] The experience is collected after the kickoff meeting (initial survey) and after completing all participation activities of the PPI project (end project survey).

Initial Survey Advisors

Survey Instructions	<input type="radio"/> English <input type="radio"/> Deutsch
Have you worked as a patient/clinician advisor on a research project prior to this one?	<input type="radio"/> Yes <input type="radio"/> No
Please describe your experience as patient/clinician advisor.	_____
Was the research team introduced to you?	<input type="radio"/> Yes <input type="radio"/> No
Did someone of the research team introduce you to the other project advisors?	<input type="radio"/> Yes <input type="radio"/> No
Was the SALuBRITY patient and public involvement (PPI) project described to you before you started working with the team?	<input type="radio"/> Yes <input type="radio"/> No
Was there enough time for you to learn about the SALuBRITY PPI project before you agreed to participate as patient/clinician advisor?	<input type="radio"/> Yes <input type="radio"/> No
Was there enough time for you to get to know the other project advisors before the SALuBRITY PPI project started?	<input type="radio"/> Yes <input type="radio"/> No
Were the communication tools explained to you before the SALuBRITY PPI started?	<input type="radio"/> Yes <input type="radio"/> No
Did you and the research team discuss your role on the team?	<input type="radio"/> Yes <input type="radio"/> No
Were the roles of the other members of the project team explained to you?	<input type="radio"/> Yes <input type="radio"/> No
Do you feel you are equipped to contribute to the SALuBRITY PPI project?	<div style="display: flex; justify-content: space-between; align-items: center;"> not at all totally </div> <div style="text-align: center;">  </div> <div style="text-align: center; font-size: small;"> (Place a mark on the scale above) </div>

End Survey Advisors

Survey Instructions

☐ English
☐ Deutsch

How comfortable do you think you are now with your understanding of the SALuBRITY patient and public (PPI) project?

very uncomfortable

very comfortable

(Place a mark on the scale above)

How comfortable did you feel speaking up in the meetings?

very uncomfortable

very comfortable

(Place a mark on the scale above)

Did you feel the team listened to you and absorbed your input?

☐ Yes ☐ No

Did any of the researchers on the team have problems dealing with patient/clinician partners?

☐ Yes ☐ No

What was the nature of the problem?

Did the research team work with you to accommodate for your challenges and ensure that it is easy for you to participate?

☐ Yes ☐ No

In your opinion, did your insights and comments impact the decisions of the future SALuBRITY trial?

never

definitely

(Place a mark on the scale above)

Did you share your personal experience as a patient/clinician as part of your role as advisor on the SALuBRITY PPI project?

☐ Yes ☐ No

What preparation would have been useful to have before being involved in this PPI project?

If you could start over again as a patient/clinician advisor, what would you do differently?

What 3 things did you learn from the experience as a patient/clinician advisor on a multidisciplinary team?

1

2

3

What 3 things could the research team have done to improve your experience?

1

2

3

Do you feel the patient/clinician partnership was productive and enriched the quality and relevance of the SALuBRITY trial?

☐ Yes ☐ No

Do you have any concerns about partnering with researchers at this point?

☐ Yes ☐ No

What was most challenging when partnering with researchers?

Where do you think your involvement mattered the most?

For peer review only

Initial Survey Researchers

Survey Instructions

☐ English
☐ Deutsch

Have you worked with patient and/or public advisor on a research project prior to this one?

☐ Yes
☐ No

Please describe your experience with patient and/or public advisors.

Did you establish a profile of the type of person you wanted as a patient/caregiver partner prior to looking for candidates?

☐ Yes
☐ No

Was there enough time for the patients/clinicians to learn about the SALuBRITY PPI project before they agreed to participate as patient/clinician advisor?

☐ Yes
☐ No

Was there enough time for the patient/clinician advisors to get to know the other project advisors before the SALuBRITY PPI project startet?

☐ Yes
☐ No

Do you feel you and your team are well prepared to work with patient/clinician advisors on this SALuBRITY PPI project?

not at all

totally

(Place a mark on the scale above)

End Survey Researchers

Survey Instructions

☐ English
☐ Deutsch

How comfortable do you think patient/clinician advisors are with their understanding of the SALuBRITY PPI project?

very
uncomfortable very comfortable

=====

(Place a mark on the scale above)

Did the patient/clinician advisors speak up and contribute at most meetings?

very
uncomfortable very comfortable

=====

(Place a mark on the scale above)

Did you feel you and the research team listened to and absorbed the inputs of the patient/clinician advisors?

☐ Yes ☐ No

Did any of the researchers on the team have problems dealing with patient/clinician partners?

☐ Yes ☐ No

What was the nature of the problem?

Did the patient/clinician advisors' comments during the member-checking process affect the final outcome of the SALuBRITY PPI Project?

☐ Yes
☐ No

Did you work with the patient/clinician advisors to accommodate for their challenges and ensure that it is easy for them to participate?

☐ Yes ☐ No

In your opinion, did the insights and comments of the patient/clinician advisors impact the decisions of the SALuBRITY trial?

never definitely

=====

(Place a mark on the scale above)

Did the patient/clinician advisors share their personal experience as a patient or clinician on the SALuBRITY PPI project?

☐ Yes ☐ No

Did you feel you and your team were well prepared to work with patient/clinician advisors on the SALuBRITY PPI project?

☐ Yes ☐ No

If you could start over again, what would you do differently?

What 3 things did you learn from the experience of partnering with patients/clinicians?

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2

3

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60

What 3 things could be done better to improve your experience?

1 _____

2 _____

3 _____

Do you feel the patient/clinician partnership was productive and enriched the quality and relevance of the SALuBRITY trial? ☐ Yes ☐ No

Do you have any concerns about partnering with patients/clinicians at this point? ☐ Yes ☐ No

What was most challenging when partnering with patient/clinician advisors? _____

Where do you think patient/clinician involvement mattered the most? _____